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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,022	11/25/2003	Mary Ann Lukas-Laskey	04012.0384	3995

22852 7590 07/14/2005

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,022	LUKAS-LASKEY ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-28-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.0-D

Applicants' Response filed April 11, 2005 is acknowledged. Claims 1-30 remain under consideration.

An Information Disclosure Statement, which had not been scanned prior to the first Office Action, is further acknowledged and has been reviewed to the extent each reference is a proper citation on a U.S. patent. All references have been considered.

In the last Office Action it was asserted the reissue oath/declaration filed with this application is defective. The error that is relied upon to support the reissue application is not an error upon which a reissue can be based. See 37 CFR 1.175(a)(1) and MPEP § 1414.

Claims 1-30 were rejected as being based upon a defective reissue declaration under 35 U.S.C. 251.

In paragraph 9 of their declaration, Applicants state the error upon which reissue is based is the failure in the claims of the U.S. Patent 5,902,821 to recite daily administration of third dosages of carvedilol to a patient for a maintenance period "to decrease a risk of mortality caused by congestive heart failure."

The preamble already states "decreasing mortality". It was asserted the error recited would only be a semantic altering of the wording already in the preamble. Further, since mortality is absolute, it was suggested Applicants consider claim language directed to reducing the occurrence of mortality from congestive heart failure.

In response, Applicants argue the cited error is not merely a semantic alteration to the extent that claims in the original patent could be interpreted such that the preamble is not a limitation. The body of the claim does not merely repeat the

preamble. Applicants rejected a suggestion by the Examiner to amend claim language to "decrease a risk of mortality caused by congestive heart failure."

Applicants' arguments are not persuasive. The error specified in the Reissue Declaration is not proper within the meaning of 35 U.S.C. 251 and 37 CFR 1.175.

In the last Office Action benefit under 35 U.S.C. 119(a) of DE 195 03 995 having a foreign application priority date of February 8, **1985** was noted.

In response, Applicants state an Application Data Sheet is being filed herewith to correct and clarify the discrepancy.

No Application Data Sheet is noted.

The rejection of claims 1-30 of record under 35 U.S.C. 251 is maintained.

Claims 1-30 were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for most of the recited limitations in the claims, does not reasonably provide enablement for "said maintenance period is greater than six months" in relation to administration of third dosages. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The limitation added in claim 1 relating to the third dosages, "said maintenance period is greater than six months", lacks clear support. In column 5 a maintenance dose is set forth that follows two earlier periods of treatment, but no time period for administration is given. In column 7, lines 56-57, a six to 12 month maintenance period is given, but is not directly related to the maintenance dosage.

None of the examples exemplifies or clarifies this limitation. Claims 1, 7, 10, 20 and 26 recite no period of time for administration of carvedilol or fail to recite an upper limit in terms of the time period for treatment.

Applicants argue it is not a requirement for a specification to describe how to make and use every possible variant of the claimed invention. Applicants urge it is within the level of skill in the art based on the disclosed maintenance dose and maintenance period to provide carvedilol for a third or maintenance period of greater than six months. Various sections of the specification are cited by Applicants to provide support for a third dosing (maintenance) period. In particular, the discussion relating to column 5, wherein a third drug administration period is described with a dosage range of 10-100 mg of carvedilol. A maintenance dose is defined on column 5, lines 32-33. A maintenance period is defined on column 7, lines 56-57.

Applicants' arguments are persuasive. The rejection of record under 35 U.S. C. 112, first paragraph, is withdrawn.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Monday to Friday from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at telephone number 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

July 5, 2004